UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,554	01/23/2002	James S. Neumiller	1023-029US01	8831

28863 7590 07/23/2004

SHUMAKER & SIEFFERT, P. A.
8425 SEASONS PARKWAY
SUITE 105
ST. PAUL, MN 55125

EXAMINER	
MATTHEW, AARON D	

ART UNIT	PAPER NUMBER
2114	

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/056,554	NEUMILLER ET AL.	
	Examiner	Art Unit	
	Aaron D Matthew	2114	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/23/2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 April 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-31 have been examined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 3, 7, 9, 11,13, 17, 19, 21, 24, 28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hood, Jr., (U.S. 5,746,203), and further in view of applicant's admitted prior art.

Regarding claim 21, Hood, Jr. teaches a medical device, ("patient monitor", see col. 1, line 9), comprising a first functional module comprising a first embedded processor, (note Figure 1, CPU 12), configured to generate a handshake signal, (see col. 2, lines 5-8), and a second functional module comprising a second embedded processor, (note Figure 1, processor 28; also note col. 1, lines 58-60 in which failsafe supervisor system is implemented in a separate one-chip module), configured to receive the handshake signal, (see col. 2, lines 13-19), and to power down said first embedded processor into a safe state when the handshake signal is not provided within a prescribed time interval, (note col. 2, lines 45-53).

Hood, Jr. fails to teach that the second embedded processor is configured to reset the first embedded processor when the handshake signal is not provided within a prescribed time interval.

Applicant's admitted prior art teaches a medical device in which a watchdog timer resets a first embedded processor when a handshake signal is not detected within a prescribed time interval, (see page 2, lines 2-5).

Hood, Jr. is considered analogous to applicant's admitted prior art as both pertain to watchdog timer supervision of a processor in a medical device.

As Hood, Jr. teaches that said second embedded processor is able to both power up and power down said first embedded processor, one of ordinary skill in the art, in view of applicant's admitted prior art, would have clearly recognized that the step of powering down said first embedded processor upon the detection of failure could be replaced with the step of resetting said first embedded processor. Applicant's admitted prior art teaches a medical device in which the cause of failure can be corrected by resetting said first embedded processor. The step of automatically resetting the first embedded processor to correct the cause of failure eliminates the requirement of having an external operator monitor the device. One of ordinary skill in the art would have been motivated to include the step of resetting said first embedded processor in the system disclosed in Hood, Jr. in the event that said step

of resetting would correct the cause of failure, in order to eliminate the requirement of an external operator monitoring the device.

Regarding claims 1 and 11, the method and processor-readable medium containing processor-executable instructions described in these claims are rejected based on the same rationale applied above in reference to claim 21. The functionality of both the method and the processor-readable medium containing processor-executable instructions is identical to the functionality of the medical device discussed above.

Regarding claim 24, Hood, Jr. teaches that the medical device of claim 21 comprises output hardware, (note col. 2, lines 2-11), wherein at least one of the first and second embedded processors is configured to disable the output hardware when the handshake signal is not provided within the prescribed time interval, (note col. 4, lines 29-32).

Hood, Jr. fails to teach that said output hardware is therapy output hardware.

Applicant's admitted prior art teaches a medical device comprising therapy output hardware wherein at least one of the first and second embedded processors is

configured to disable the therapy output hardware when the handshake signal is not provided within the prescribed time interval, (see page 2, lines 2-6).

In view of applicant's admitted prior art, one of ordinary skill in the art would have clearly recognized the applicability of a watchdog timer system as disclosed in Hood, Jr. to a medical device comprising therapy output hardware. In the event of a fault in the medical device it would have been clearly recognized in the art that said therapy output hardware should be disabled to prevent harm to the recipient of said therapy. One of ordinary skill in the art would have considered it obvious and would have been properly motivated to combine the system disclosed in Hood, Jr. to a medical device comprising therapy output hardware in order to enable the disabling of potentially harmful output from a failed device.

Regarding claims 3 and 13, the method and processor-readable medium containing processor-executable instructions described in these claims are rejected based on the same rationale applied above in reference to claim 24. The functionality of both the method and the processor-readable medium containing processor-executable instructions is identical to the functionality of the medical device discussed above.

Regarding claim 28, Hood, Jr. teaches that the medical device comprises a system controller and a patient parameters module, (note Figure 1, elements 12 and 16).

Hood, Jr. fails to teach that the medical device comprises a therapy control module, and a user interface module.

Applicant's admitted prior art teaches that the medical device comprises a therapy control module, a user interface module and a patient parameters module, (see page 1, lines 17-19).

As outlined in applicant's admitted prior art, the therapy control module controls operation of the defibrillator electrodes, and the user interface module receives input and presents output to medical personnel. One of ordinary skill in the art would have clearly recognized the advantages offered by the two modules in a medical device controlling the output of therapy. The use of a user interface is well known in the art in a device that offers an external operator control over certain functions in the device. Hood, Jr. discloses the use of parameter modules, (Fig. 1, element 16), however, one of ordinary skill in the art would have considered it obvious to include any number of modules according to the functions of a given medical device in view of Hood, Jr. Therefore, in view of applicant's admitted prior art, one of ordinary skill in the art would have been properly motivated to include a user interface module and a therapy control module in a medical device as disclosed in Hood, Jr.

Regarding claims 7 and 17, the method and processor-readable medium containing processor-executable instructions described in these claims are rejected based on the same rationale applied above in reference to claim 28. The functionality of both the method and the processor-readable medium containing processor-executable instructions is identical to the functionality of the medical device discussed above.

Regarding claim 30, see Hood, Jr. col. 3, lines 50-57, wherein the patient parameters module is configured to obtain ECG information, vital sign measurements, non-invasive blood pressure measurements, and SpO_2 information from a patient.

Regarding claims 9 and 19, the method and processor-readable medium containing processor-executable instructions described in these claims are rejected based on the same rationale applied above in reference to claim 30. The functionality of both the method and the processor-readable medium containing processor-executable instructions is identical to the functionality of the medical device discussed above.

3. Claims 2, 12, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hood, Jr. in view of applicant's admitted prior art as applied to claims 1, 11 and 21 above, and further in view of Nitschke et al. (U.S. 6,463,555).

Regarding claims 22 and 23, Hood, Jr. in view of applicant's admitted prior art fails to teach that at least one of the first and second functional modules comprises a windowed watchdog timer, or that at least one of the first and second embedded processors is configured to reset when the handshake signal is provided before a minimum time or after a maximum time.

Nitschke et al discloses a windowed watchdog timing circuit that monitors the function of a processor, and resets the processor when a handshake signal is provided before a minimum time or after a maximum time, (see col. 2, lines 27-34).

Nitschke et al, Hood Jr. and applicant's admitted prior art are considered to be analogous in that they all teach system for monitoring the operation of a processor for failure using a watchdog timer.

It has already been shown that Hood, Jr. in view of applicant's admitted prior art discloses a medical device in which a second processor is configured to reset a first processor when the handshake signal is provided after a maximum time interval. Nitschke et al shows that a processor being monitored by a watchdog timer could

also be in error if a handshake signal is received before a minimum time. Such a situation could arise if the program in the processor enters an erroneous loop. Monitoring a processor for a handshake signal provided before a minimum time offers an additional check on the operation of the processor, and improves the reliability of the watchdog timer in detecting a failure event in the processor. One of ordinary skill in the art would have clearly recognized the benefits of using a windowed watchdog timer to monitor a processor for failure, in view of Nitschke et al, and would have been properly motivated to include said timer in the device taught by Hood, Jr. in order to improve the system's reliability in detecting faults in a processor.

Regarding claims 2 and 12, the method and processor-readable medium containing processor-executable instructions described in these claims are rejected based on the same rationale applied above in reference to claims 22 and 23. The functionality of both the method and the processor-readable medium containing processor-executable instructions is identical to the functionality of the medical devices discussed above.

4. Claims 4-6, 14-16 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hood, Jr. in view of applicant's admitted prior art as applied to claims 1, 11 and 21 above, and further in view of Sirazi et al., (U.S. 4,586,179).

Regarding claim 25, Hood, Jr. in view of applicant's admitted prior art fails to teach that the medical device comprises a voltage monitor configured to detect an abnormal power condition and to disable therapy output hardware in response to the abnormal power condition.

Sirazi et al teaches a combination watchdog timer and input voltage level detector circuit coupled to a microprocessor, (see Abstract, lines 1-2). The voltage monitor is configured to detect an abnormal power condition and to disable the microprocessor in response to the abnormal power condition, (note col. 3, lines 38-43).

Sirazi et al, Hood, Jr. and applicant's admitted prior art are considered analogous in that they all pertain to a watchdog timing system used to monitor a processor for failure.

It has already been shown that combining therapy output hardware as disclosed in applicant's admitted prior art to the medical device disclosed in Hood, Jr., would have been obvious to one of ordinary skill in the art. Siraze et al teaches a microprocessor that will not function properly in an abnormal power condition, (col.

3, lines 40-43). One of ordinary skill in the art would have clearly recognized, in view of Siraze et al, that a watchdog timer combined with a voltage monitor, (see col. 7, lines 36-39), offers an advantage of preventing a microprocessor from attempting to operate in an abnormal power condition, thus preventing the microprocessor from functioning improperly. One of ordinary skill in the art would have clearly recognized that the system taught by Hood, Jr., in view of applicant's admitted prior art, relies heavily on power for performing its therapy output function, and would not function properly in an abnormal power condition. It would have been further recognized that an abnormal power condition could create a harmful situation for a patient receiving therapy. Therefore, in view of Siraze et al, one of ordinary skill in the art would have been properly motivated to combine a voltage monitor with the watchdog timer circuitry of Hood, Jr., in view of applicant's admitted prior art, in order to prevent the therapy output hardware from functioning improperly and potentially harming a patient.

Regarding claims 4 and 14, the method and processor-readable medium containing processor-executable instructions described in these claims are rejected based on the same rationale applied above in reference to claim 25. The functionality of both the method and the processor-readable medium containing processor-executable instructions is identical to the functionality of the medical device discussed above.

Regarding claims 26 and 27, Hood, Jr., in view of applicant's admitted prior art, fails to teach a voltage monitor further configured to detect a voltage of the medical device and to selectively disable therapy output hardware as a function of the detected voltage.

Siraze et al teaches that the voltage monitor is configured to detect a voltage of a device, (note col. 3, lines 7-10), and to selectively disable hardware as a function of the detected voltage, (note col. 3, lines 26-34).

As it has been shown the advantages of disabling therapy output hardware, (as disclosed in Hood, Jr., in view of applicant's admitted prior art), in response to an abnormal power condition, it would have been equally obvious to one of ordinary skill in the art to configure the voltage monitor to selectively disable therapy output hardware as a function of a detected erroneous voltage, (refer to discussion of claim 25).

Regarding claims 5, 6, 15 and 16, the methods and processor-readable media containing processor-executable instructions described in these claims are rejected based on the same rationale applied above in reference to claims 26 and 27. The functionality of both the methods and the processor-readable media containing

processor-executable instructions is identical to the functionality of the medical devices discussed above.

5. Claims 8, 18, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hood, Jr. in view of applicant's admitted prior art as applied to claims 7, 17 and 28 above, and further in view of official notice.

Regarding claim 29, Hood, Jr., in view of applicant's admitted prior art, fails to teach that the user interface module is communicatively coupled to at least one of a keyboard, a display screen, and a strip chart recorder.

Examiner takes official notice that it would have been well known in the art that a user interface module is necessarily coupled to a number of input/output devices for facilitating communication with an external operator. Among those input/output device well known in the art for such a coupling are a keyboard, a display screen, and a strip chart recorder.

One of ordinary skill in the art, in view of official notice, would have considered it obvious to communicatively couple at least one of a keyboard, a display screen, and a strip chart recorder with a user interface module. As would have been well known in the art, the functionality of a user interface module is only available to a user if the

user has some means of providing information to, and obtaining information from, the module. Communicatively coupling at least one of a keyboard, a display screen, and a strip chart recorder, offers the advantage of allowing an external operator to communicatively interact with the user interface module in a medical device. One of ordinary skill in the art would have been properly motivated to include said couplings in order to facilitate communication between the user interface module and an external operator.

Regarding claims 8 and 18, the method and processor-readable medium containing processor-executable instructions described in these claims are rejected based on the same rationale applied above in reference to claim 29. The functionality of both the method and the processor-readable medium containing processor-executable instructions is identical to the functionality of the medical device discussed above.

6. Claims 10, 20 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hood, Jr. in view of applicant's admitted prior art as applied to claims 1, 11, and 21 above, and further in view of Olson et al., (U.S. 5,919,212).

Regarding claim 31, Hood, Jr., in view of applicant's admitted prior art, fails to teach that the medical device is an automated external defibrillator, (AED).

Olson et al teaches an AED comprising a watchdog timer, (see Abstract).

Applicant's admitted prior art teaches the advantage of using a watchdog timer in a defibrillator in order to improve reliability, (note page 1, lines 27-29). Olson et al teaches that automated external defibrillators should be periodically checked for faults, (col. 1, lines 27-28), in order to prevent the AED from malfunctioning at a critical time. One of ordinary skill in the art would have considered it obvious to replace the watchdog system disclosed in Hood, Jr., in view of applicant's admitted prior art, with the watchdog system of the automated external defibrillator of Olson et al, as it provides an alternative means of periodically checking an AED for faults. Moreover, one of ordinary skill in the art would have been motivated to do so in order fulfill a recognized need in the art to prevent an AED from malfunctioning at a critical time.

Regarding claims 10 and 20, the method and processor-readable medium containing processor-executable instructions described in these claims are rejected based on the same rationale applied above in reference to claim 31. The functionality of both the method and the processor-readable medium containing processor-executable instructions is identical to the functionality of the medical device discussed above.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Daniels et al., (U.S. 4,618,953) teaches a watchdog circuit for improving the possibility of recovery from failures comprising a single-chip processor configured to reset a main processor if the former does not receive a status signal within a predetermined period.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron D Matthew whose telephone number is (703) 605-1211. The examiner can normally be reached on Mon-Fri, from 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert W Beausoliel can be reached on (703) 305-9713. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Aaron D Matthew
Examiner
Art Unit 2114

ADM

ROBERT BEAUSOLIEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2100